

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
10 October 2002 (10.10.2002)

PCT

(10) International Publication Number
WO 02/078552 A1

(51) International Patent Classification⁷: **A61B 17/42**,
A61F 2/08, A61D 9/02

(21) International Application Number: **PCT/AU02/00369**

(22) International Filing Date: **27 March 2002 (27.03.2002)**

(25) Filing Language: **English**

(26) Publication Language: **English**

(30) Priority Data:
PR 4065 28 March 2001 (28.03.2001) AU

(71) Applicant and

(72) Inventor: **KALADELFOS, George** [AU/AU]; 17
Brighton Avenue, Toronto, Western Australia 2283 (AU).

(74) Agent: **FREEHILLS CARTER SMITH BEADLE**;
Level 32, MLC Centre, 19-29 Martin Place, Sydney, New
South Wales 2000 (AU).

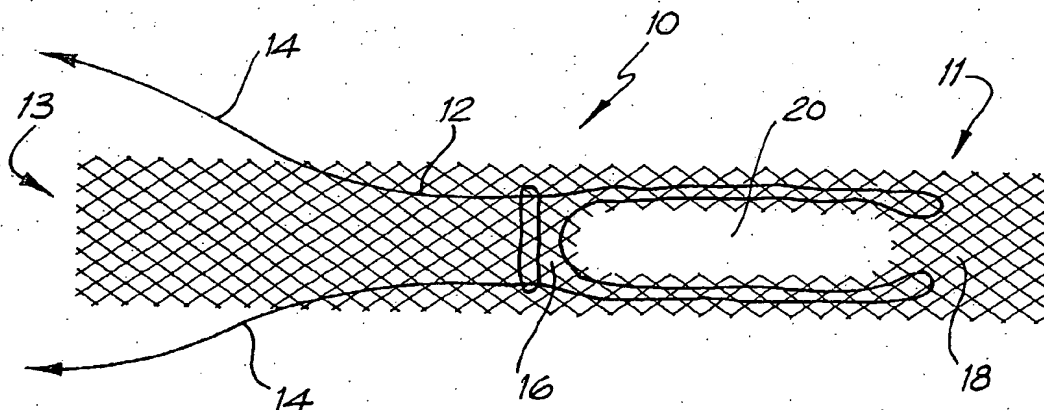
(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: **TREATMENT OF VAULT PROLAPSE**



(57) Abstract: Apparatus for forming an artificial tie or ligament between different internal parts within a mammalian body, the apparatus comprising a strip (10) of preferably mesh type fabric formed of a material which is suitable for remaining in the body, and a drawstring (12) which is looped between different points along the length of the strip (10). By drawing the drawstring (12) the length of the strip (10) can be reduced. Opposite ends of the strip (11, 13) are in use attached to the different internal parts, and then those parts can be pulled together by applying tension to the drawstring (12), and once the length of the strip (10) has been reduced, tying off the drawstring (12) to hold the strip (10) in its reduced length condition. The apparatus is specifically useful for use in a method of treating vault or vaginal prolapse. The invention extends to a method of treating vault or vaginal prolapse.

WO 02/078552 A1

Treatment of Vault Prolapse

Field of the invention

This invention relates to the treatment of vaginal or vault prolapse and to a device suitable for use in such treatment. The device might be used in other medical procedures.

Background of the invention

Vault or vaginal prolapse is a condition which occurs in women who have undergone a medical procedure such as a hysterectomy which has resulted in the utero-sacral ligaments which hold the vagina in position within the body cavity being severed or damaged. The result of such damage is that the vagina has a tendency to invert which is uncomfortable and unhealthy, and renders the vagina unsuitable for intercourse.

The condition has in the past been treated using one of various different procedures. Abdominal colposacropexy for example involves abdominal surgery which is undesirable. Zacharin's abdominal operation is another documented procedure in which the vagina is attached directly to the pelvic floor. Vaginal enterocele repair involves the attachment of the vault to the ileococcygeus muscle followed by posterior repair. Petros' infra-coccygeal sacropexy uses a nylon tape to "recreate" the utero-sacral ligaments.

Procedures performed via abdominal incision are particularly invasive and therefore not the preferred form of treatment. Procedures performed vaginally are however difficult to perform due to the close confines in which the procedure needs to be performed and the narrow passageway through which the surgeon must operate. It will be appreciated that attaching the distal end of the vagina to the pelvic floor in such a manner that the vagina is properly aligned and that the artificial ligaments thus created are of correct length and tension requires a great deal of skill and dexterity. An aim of the present invention is to facilitate the aforementioned vaginal procedure.

Summary of the invention

In broad terms the invention comprises a strip of fabric or mesh formed of a material adapted to remain within the body cavity after a procedure has been performed therewith, the strip incorporating a drawstring which extends between at least two points separated lengthwise

along the strip, the drawstring being configured such that tension applied to the drawstring will assist in causing the length of the strip between the two points to be reduced.

The strip is preferably made of a light mesh formed of an absorbable or non-absorbable thread. Suitable material might comprise proprietary materials such as Vypro™ or Prolene™ or Vycral™. The mesh openings are probably between 1mm and 8 mm in diameter.

The drawstring is preferably threaded in and out, through the mesh openings, so that tension applied to the drawstring will tend to cause the strip to adopt a gathered configuration. The drawstring is preferably threaded in such a manner that the two ends of the drawstring are aligned parallel with each other and aligned with the length of the strip, the two ends being adapted to be tied together to retain the strip in its reduced length condition. The drawstring may be configured so that a mechanical advantage is obtained by applying tension to the drawstring. The configuration might comprise looping the drawstring at least twice between said points so that drawing the drawstring a certain length will reduce the length of the strip by half that length.

The strip may have a central region removed therefrom and the drawstring may be looped around said central region.

The invention extends to a method of treating vaginal prolapse which comprises attaching a strip of the type defined above between the pelvic floor and the vault, using the drawstring to reduce the length of the strip, thereby pulling the vault towards the pelvic floor, and tying the drawstring off to maintain the strip in its reduced length condition, thereby forming a tie between the vault and the pelvic floor.

In the preferred form of the invention two strips are attached in this manner to the pelvic floor, on opposite sides of the rectum from opposite sides of the vault. The strip or strips are preferably attached to the cardinal ligament area of the vault.

Where the procedure is performed vaginally it will first be necessary to open the posterior floor of the vagina to obtain access to the pelvic floor.

It will be appreciated that the strip of the invention could well have application in surgical procedures in addition to that of treatment of vault prolapse.

These and further features of the invention will be made apparent from the description of preferred embodiments thereof given below by way of example. In the description reference is

made to the accompanying drawings, but the specific features shown in the drawings should not be construed as limiting on the invention.

Brief description of the drawings

Figure 1 shows a plan view of a strip of mesh according to the invention;

Figure 2 shows a plan view of another strip of mesh according to the invention;

Figure 3 shows a perspective view of a strip according to the invention fixed in portion between two locations in a body, the strip being in its reduced length condition;

Figure 4 shows a sectional side view of a patient with two strips according to the invention in place on opposite sides of the vagina; and

Figure 5 shows a similar view to that of Figure 4 but with the strips in their reduced length condition after the drawstrings have been tightened and tied off.

Detailed description of the embodiments

Referring initially to Figures 1 to 3, a strip 10 according to the invention is formed of a length of mesh material which conveniently comprises a wide mesh formed of a Vypro[®] thread and is adapted to be left permanently within the body as a permanent ligament. The strip 10 has a first end 11 which in use will be attached to the pelvic floor of a patient, and a second end 13 which in use will be attached to the vaginal wall of the patient. The manner in which the strip will be used is described in more detail below.

A drawstring 12 is threaded in and out through the mesh openings so as to form an M-shaped double loop, with the two free ends 14 of the drawstring extending parallel with each other towards the one end 13 of the strip. The effect of the drawstring being in this double loop configuration is that the drawstring connects together two points of the strip, numbered 16 and 18 in the drawings. It will be appreciated that pulling on the ends 14 of the drawstring will have the effect of shortening the two loops, causing the strip to gather or pleat between the two points 16 and 18, thereby effectively shortening the strip.

The strip has a central portion 20 in which the mesh material has been removed, the central portion being located in the region of the strip between the two points 16 and 18. Removing the mesh from the central portion has the effect of reducing the quantity of mesh material in the region of the strip which is gathered after pulling on the drawstring.

It will be appreciated that the double loop configuration of the drawstring is selected so that a mechanical advantage is obtained when pulling on the drawstring to thereby facilitate the shortening of the strip. Pulling the two ends of drawstring a set length will shorten the strip by half of that length. Of course, other configurations of drawstring threading will achieve a different mechanical effect.

In Figure 2 a similar strip 38 is depicted to that shown in Figure 1 but the drawstring 40 has only a single free end 42 whilst the other end 44 is secured to the mesh. The drawstring 40 is threaded through the mesh openings to form one and a half loops around the central opening 46 and pulling on the end 42 in the direction of arrow 48 will cause the drawstring to tighten around the central opening 46 thereby effectively reducing the length of the strip. A disadvantage of this embodiment is that tying off the drawstring is more difficult, but in some applications this might not be a problem and may be advantageous.

Figure 2 also shows a variation in which the drawstring 40A is not looped back around the opening 46 to terminate at its anchored end 44. Rather, that portion of the drawstring has a free end 42A so that the entire drawstring has a U-shaped configuration. The drawstring may optionally be anchored at the bight of the U. Tightening of the drawstring is achieved by pulling on the free-ends 42 and 42A in the direction of arrows 48 and at the same time pushing on the mesh in the direction of arrow 49. This is achieved by pushing the vaginal wall 26 towards the pelvic floor 28, and thereafter tying off the free ends 42 and 42A of the drawstring.

A yet further embodiment is illustrated in chain outline at 50, and essentially represents a continuation of the drawstring 40 in mirror image having the mechanical advantage of that drawstring configuration with the added advantage of symmetrical gathering up of the mesh and the ability to tie off both free ends 42 and 51.

As shown in Figure 3 of the drawings the strip 10 is attached via first end 11 to a first location point which, in the treatment of vault prolapse, will be the pelvic floor 28. The other end 13 will be attached to the other attachment point which, in the treatment of vault prolapse, will be the vaginal wall 26. It will be noted that the end 13 comprises a length of mesh material which is about half of the entire length of the strip 10. The drawstring 12 is threaded through the first end 11 of the strip. Clearly, the second end 13 of the strip may be attached at any point along its length so as to be able to accommodate physiological differences in female patients. The commonest point of attachment of the mesh of the vaginal vault is adjacent the central

opening 20, that is, at location 16 on the mesh. The mesh may be reinforced at this point to provide for more secure attachment to the vaginal vault. Excess strip material can, if desired, be cut from the end 13 either prior to or during the attachment procedure.

Once the ends 11 and 13 have been attached to their respective locations in the body the drawstring 12 will be pulled up and the two ends tied off. It will be noted from Figure 3 that the end 11 has been gathered up, considerably reducing the overall length of the strip 10. The gathered portion of the strip is indicated at numeral 15.

In use for treatment of vault prolapse, two strips will be connected between opposite sides of the vagina and the pelvic floor. The arrangement is clearly shown in Figures 4 and 5 of the drawings.

The first stage of the procedure is to open the posterior vaginal wall 26 to obtain access to the pelvic floor 28. The pelvic floor 28 is exposed on either side of the rectum 30 thereby providing locations where two strips 10 can be attached to the pelvic floor.

The respective ends 11 of the two strips are then attached to the exposed locations on the pelvic floor by suturing. The sutures can simply attach the mesh material itself to the pelvic floor, but preferably the sutures pass around the drawstring so as to form a secure attachment point for the drawstring of each strip. Thereafter the other ends 13 of the two strips are attached to the cardinal ligament area on each side of the vault. Clearly, exactly where along the length of the strip the attachment to the vault is made will depend on the patient's physiology, and typically the actual attachment point will be some distance away from the distal end 13.

Once both ends of both strips 10 have been attached between the pelvic floor and the vault the surgeon will begin closing the posterior vaginal wall. Once partially closed the drawstrings can be used to pull the vault closer to the pelvic floor. Pulling on the drawstrings will, as discussed above, shorten the strips, and since the strips connect the vault to the pelvic floor, the vault will effectively be pulled towards the pelvic floor. Since there are two strips, each with its respective drawstring, the surgeon can ensure that the vagina is correctly aligned and positioned. The drawstrings allow the final alignment and positioning to be done when the vaginal wall incision is partially closed making the whole operation that much easier to perform.

Once the vagina has been pulled into the correct position, the two ends of each drawstring will be tied together, thereby securing each strip in its reduced length condition, permanently holding the vagina in position. The strips are made from a material specifically adapted to be left in place in the body, and will in time form artificial ligaments connecting the vagina to the pelvic floor.

The posterior vaginal wall will then be completely closed and if required the perineal body can be refashioned. Very little if any vaginal mucosa need be excised. As mentioned above, it is desirable that the procedure is performed vaginally since this greatly reduces patient morbidity.

Figure 5 depicts the two strips in position after the drawstrings have been tied off.

Clearly there may be many variations to the above described embodiment without departing from the scope of the invention. Clearly the strip can be configured differently to that described herein, and can be made of a different material. For example, the two individual strips 10 may converge at their base in the manner indicated in broken outline at 54 in Figure 3, resulting in Y-shaped configuration with the individual drawstrings being fed through each arm of the Y.

As mentioned above, the drawstring can be threaded differently. However, the advantage of being able to pull the vagina into position at a relatively late stage of the operation will greatly facilitate achieving optimal alignment of the vagina, even though the operation is performed vaginally.

It is envisaged that a mesh or fabric in strip form will best be used to form the apparatus of the invention. However, it should be appreciated that in some applications a strip as such might not be necessary. For example, a longitudinally extending narrow tube might be used in some applications, or a chord-like elongate element might also be used. The drawstring will generally be connected to the ligament defining elongate element in such a way that relative sliding between the drawstring and the elongate element will result in the aforementioned length reduction of the elongate element, as the drawstring has tension applied to it.

The term "drawstring" as used herein is intended to have a broad interpretation and will include any filament that can be used to reduce the length of an element connected between two

internal parts within a body. The term "tie" likewise is to be given broad interpretation and is used to describe a connector which is able to act under tension to hold two parts together.

It will be understood that the invention disclosed and defined herein extends to all alternative combinations of two or more of the individual features mentioned or evident from the text or drawings. All of these different combinations constitute various alternative aspects of the invention.

The foregoing describes embodiments of the present invention and modifications, obvious to those skilled in the art can be made thereto, without departing from the scope of the present invention.

CLAIMS

1. Apparatus for forming an artificial tie or ligament between different internal parts within a mammalian body, the apparatus comprising a strip of flexible material adapted to remain within the body after a procedure has been performed therewith, the strip incorporating a drawstring which extends between at least two points separated lengthwise along the strip, the drawstring being configured such that tension applied to the drawstring will assist in causing the length of the strip between the two points to be reduced, and retain the strip in its reduced length condition.
2. Apparatus according to claim 1 wherein the strip comprises a fabric or mesh material.
3. Apparatus according to claim 2 wherein the strip is comprised of a light mesh formed of either an absorbable, or a non-absorbable thread.
4. Apparatus according to claim 3 wherein the mesh has openings of between 1mm and 8 mm in diameter.
5. Apparatus according to either claim 3 or 4 wherein the drawstring is threaded in and out, through the mesh openings, so that tension applied to the drawstring will tend to cause the strip to adopt a gathered configuration.
6. Apparatus according to claim 5 wherein the drawstring has a central region and two end regions, the end regions being free of the strip, the end regions being adapted to be tied together to hold the strip in its gathered configuration.
7. Apparatus according to claims 5 or 6 wherein the drawstring is configured such that mechanical advantage is obtained by applying a tension to the drawstring.
8. Apparatus according to claim 7 wherein the drawstring is looped at least twice between said points so that drawing the drawstring a certain length will reduce the length of the strip by half that length.
9. Apparatus according to any preceding claim wherein a central region of the strip, between said two points, has been removed and the drawstring is looped around said central region.
10. Apparatus according to claim 5 in which the strip is configured to adopt a gathered configuration by the additional application of force to the mesh in the direction of gathering.

11. Apparatus according to any preceding claim wherein the strip of flexible material has a Y-shaped configuration, with at least one drawstring being carried on each arm of the Y.

12. Apparatus for forming an artificial tie or ligament between different internal parts within a mammalian body, the apparatus comprising a first elongate flexible member, and a second elongate flexible member, each member being formed of a material adapted to remain for at least a significant time within the body, the second elongate flexible member being attached to the first elongate flexible member at at least two points, the attachment at at least one point being a slidable attachment such that tension applied to the second flexible member, relative to the first flexible member will cause the first flexible member to reduce in length, over at least part of its length, opposite end regions of the first elongate member being adapted to be attached to different respective parts within a said body.

13. A method of treating vaginal prolapse using at least one elongate flexible member having a drawstring extending between two points separated lengthwise along the member, the method comprising the steps of:

attaching said member between the pelvic floor and the vault,

using the drawstring to reduce the length of the member, thereby pulling the vault towards the pelvic floor, and

tying off the drawstring to maintain the member in its reduced length condition, thereby forming a tie between the vault and the pelvic floor.

14. A method according to claim 13 wherein two elongate members are attached to the pelvic floor, on opposite sides of the rectum, and to opposite sides of the vault, and the drawstrings of both elongate members are used to reduce the length of their respective elongate members, the drawstrings then being tied off.

15. A method according to claim 13 or 14 wherein the procedure is performed vaginally by opening the posterior floor of the vagina to obtain access to the pelvic floor.

16. A method of forming an artificial tie between two internal parts of a mammalian body using at least one elongate flexible member having a drawstring extending between two points separated lengthwise along the member, the method comprising the steps of:

attaching said flexible member between said parts;

using the drawstring to reduce the length of the member, thereby drawing the two parts together; and

tying off the drawstring to maintain the elongate member in its reduced length condition, thereby forming a tie between said parts.

17. Apparatus substantially as hereinbefore describe with reference to any one of the embodiments shown in the accompanying drawings.

18. A method substantially as hereinbefore described with reference to the accompanying drawings.

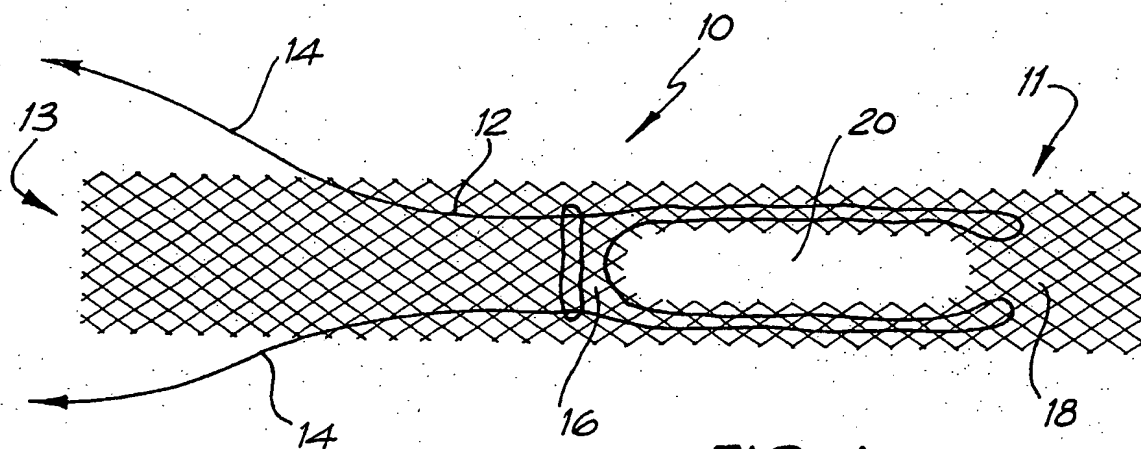


FIG. 1

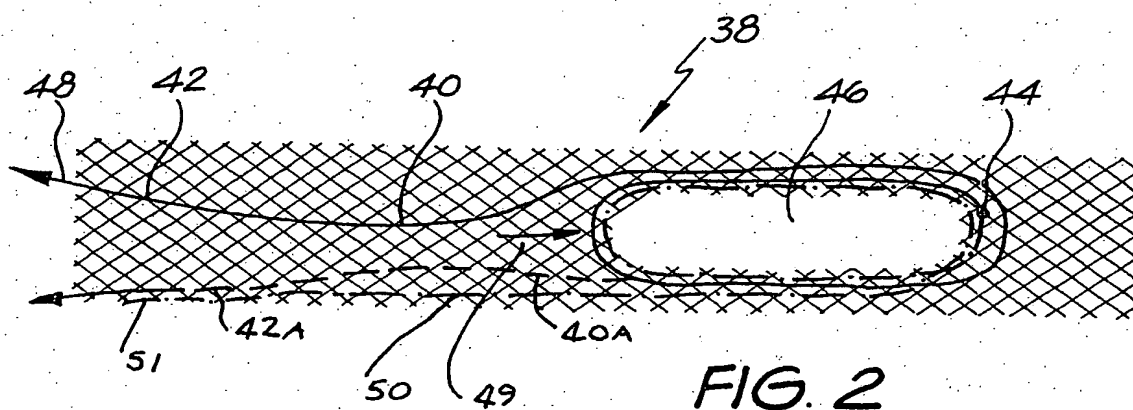


FIG. 2

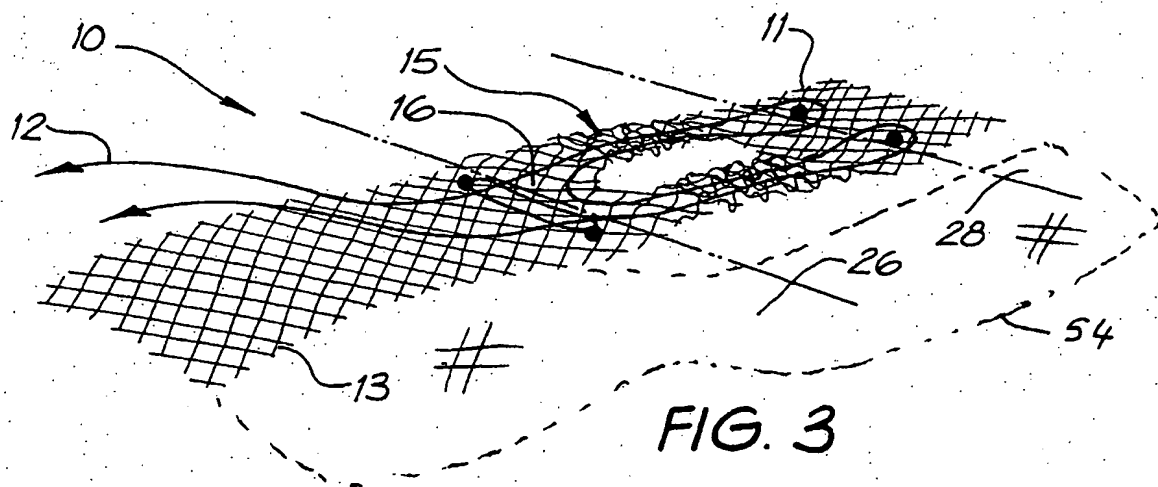
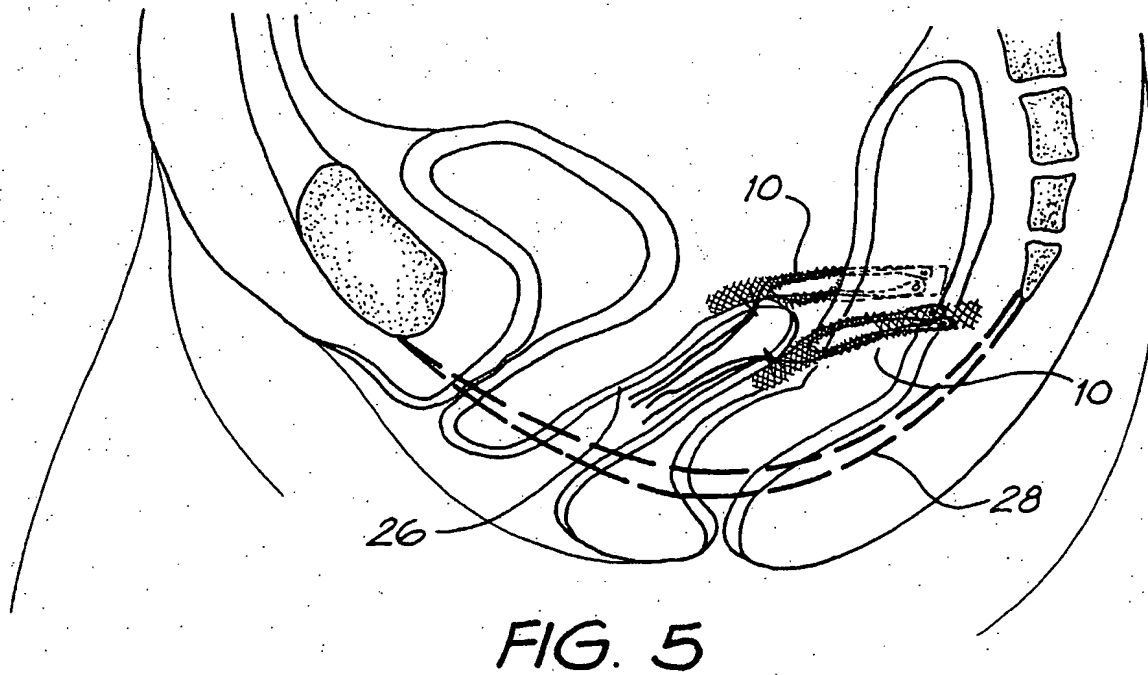
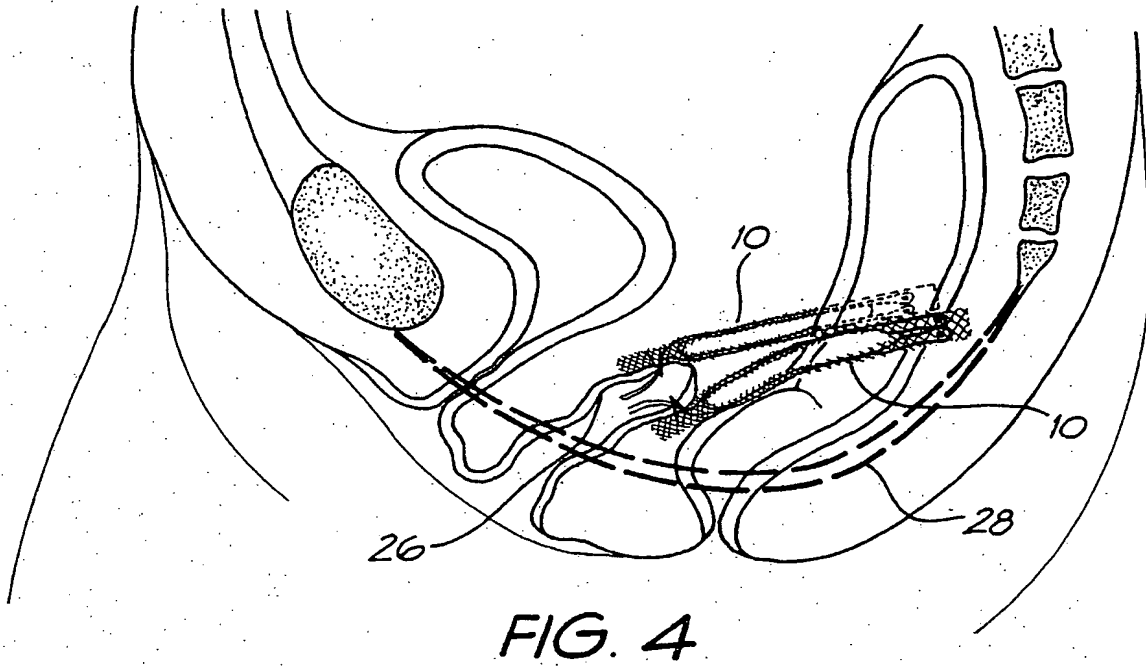



FIG. 3



BEST AVAILABLE COPY

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU02/00369

A. CLASSIFICATION OF SUBJECT MATTER				
Int. Cl. 7: A61B 17/42, A61F 2/08, A61D 9/02				
According to International Patent Classification (IPC) or to both national classification and IPC				
B. FIELDS SEARCHED				
Minimum documentation searched (classification system followed by classification symbols)				
REFER ELECTRONIC DATABASE CONSULTED BELOW				
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched				
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)				
DWPI: & keywords: vagina, prolapse, mesh, tension and similar terms				
C. DOCUMENTS CONSIDERED TO BE RELEVANT				
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.		
X	US 6039686 A (KOVAC) 21 March 2000 See column 6 line 56-column 7 line 45, and figures 8-9.	1-8, 10, 12-16		
X	WO 93/15690 A1 (MEDTRONIC INC.) 19 August 1993 See entire document.	1-10, 12, 16		
X	EP 1078601 A2 (SPIRATION INC.) 28 February 2001 See column 5 line 54-column 7 line 51.	1-10, 12, 16		
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex				
<p>* Special categories of cited documents:</p> <table style="width: 100%;"> <tr> <td style="width: 40%;"> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </td> <td style="width: 60%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p> </td> </tr> </table>			<p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p>	<p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p>
<p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p>	<p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p>			
Date of the actual completion of the international search 29 May 2002		Date of mailing of the international search report 6 JUN 2002		
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929		Authorized officer  JOHN HO Telephone No : (02) 6283 2329		

BEST AVAILABLE COPY

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU02/00369

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4428375 A (ELLMAN) 31 January 1984 See column 1 lines 43-61, and figures 2-4.	1-10, 12, 16
A	WO 00/64370 A1 (SOFRADIM PRODUCTION et al.) 2 November 2000 See entire document.	
A	US 4668233 A (SEEDHOM et al.) 26 May 1987 See entire document.	
A	WO 00/27304 A1 (SOFRADIM PRODUCTION et al.) 18 May 2000 See entire document.	

BEST AVAILABLE COPY

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU02/00369

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member	
US 6039686	US 2001000533 US 2002022841	US 6322492	US 6328686
WO 9315690	AU 35971/93 US 5674279	EP 624080 US 5306296	US 5201880
EP 1078601	AU 200053611 US 6328689	JP 2001087270 US 2001025132	AU 200072420
US 4428375	NONE		
WO 200064370	EP 1171055	FR 2792824	
US 4668233	EP 126520 EP 153831	JP 59207145 JP 60241434	US 4997434
WO 200027304	EP 1128781	FR 2785521	
END OF ANNEX			